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| APPLICATION NO.                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/797,146                          | 03/11/2004  | Timothy Dinan        | 025911-000600US     | 4330             |
| 20350                               | 7590        | 11/15/2007           | EXAMINER            |                  |
| TOWNSEND AND TOWNSEND AND CREW, LLP |             |                      | HUYNH, CARLICK      |                  |
| TWO EMBARCADERO CENTER              |             |                      |                     |                  |
| EIGHTH FLOOR                        |             |                      | ART UNIT            | PAPER NUMBER     |
| SAN FRANCISCO, CA 94111-3834        |             |                      | 1617                |                  |
|                                     |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                     |             |                      | 11/15/2007          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/797,146             | DINAN ET AL.        |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Carlic K. Huynh        | 1617                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 September 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,7,10-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 5,22 and 27 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,7,10-20,23-26,28 and 29 is/are rejected.
- 7) Claim(s) 10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>28 October 2005</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### *Status of the Claims*

1. Claims 1-35 are pending in the application, with claims 31-35 having been cancelled, in response to the restriction requirement submitted on August 10, 2007. It is noted that claims 6, 8-9, 21, and 30 have also been cancelled in a Response to Election/Restriction filed on September 10, 2007. Accordingly, claims 1-5, 7, 10-20, and 22-29 are being examined on the merits herein.

### *Election/Restrictions*

2. Applicant's election of the claims of Group I, namely claims 1-30, in the reply filed on September 10, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6, 8-9, 21, and 30-35 are cancelled in the reply filed on September 10, 2007. Election was made without traverse in the reply filed on September 10, 2007.

3. Applicants' election of: (1) major depression as a depression or other affective disorders; (2) ibuprofen as an anti-inflammatory agent; and (3) citalopram as an antidepressant, in the reply filed on September 10, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Claims 5, 22, and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on September 10, 2007.

Accordingly, claims 1-4, 7, 10-20, 23-26, 28, and 29 are examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

***Information Disclosure Statement***

The Information Disclosure Statement submitted on October 28, 2005, is acknowledged.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 7, 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van West et al. (Neuroendocrinology Letters, 1999, Vol. 20, pp. 11-17) in view of Sanchez et al. (US 2004/0192764) and Lanza et al. (US 5,912,005).

Van West et al. teach a method of treating major depression using antidepressants, specifically a selective serotonin reuptake inhibitor or SSRI (abstract and page 15). Van West et al. teach that hypothalamic-pituitary-adrenal (HPA)-axis hyperactivity and the turnover of serotonin (5-HT) contribute to depression (abstract). Thus, the antidepressant, the SSRI, acts on the HPA-axis to treat depression. Increased production of proinflammatory cytokines, such as

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interleukin-1 (IL-1), IL-6, and interferon (IFN $\gamma$ ), also play a role in depression (abstract). Van West et al. further teach that the anti-depressant has anti-inflammatory effects when used to treat major depression (page 15). The SSRI have anti-inflammatory effects through downregulation of proinflammatory cytokines, namely IL-1, IL-6, and IFN $\gamma$ , and upregulation of anti-inflammatory cytokines, such as IL-10 (abstract and page 15).

Van West et al. do not teach citalopram and ibuprofen.

Sanchez et al. is solely used to teach that citalopram is a well known antidepressant drug belonging to the class of selective serotonin reuptake inhibitors or SSRIs (page 1, paragraphs [0001]-[0002]).

Thus it would be obvious that the SSRI in Van West et al. may be citalopram.

Lanza et al. teach a method of treating depression comprising a composition comprising ibuprofen (column 9, line 60; and column 18, lines 37-44).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the compounds of Van West et al. to contain citalopram and ibuprofen because the compounds of Sanchez et al. teach citalopram and the compounds of Lanza et al. teach ibuprofen and according to Van West et al., antidepressants, which act as anti-inflammatory agents, can be used to treat major depression and according to Lanza et al., ibuprofen is present in a composition that is used to treat major depression.

The motivation to combine the compounds of Van West et al. to the compounds of Sanchez et al. and Lanza et al. is that compounds of Sanchez et al. are antidepressants and the

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compounds of Lanza et al. are anti-inflammatory agents and that such compositions can be used to treat major depression.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

5. Claims 23-26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anisman et al. (Annals of Medicine, 2003, Vol. 35, pp. 2-11) in view of Van West et al. (Neuroendocrinology Letters, 1999, Vol. 20, pp. 11-17), Sanchez et al. (US 2004/0192764), and Lanza et al. (US 5,912,005).

It is noted that the Anisman et al. reference has an on-line publication date of January 1, 2003.

Anisman et al. teach immunotherapy high doses of interleukin-2 (IL-2) and/or interferon (IFN $\gamma$ ) induce depression and that these depressive symptoms are attenuated by antidepressant treatment (abstract and page 8). Major depression is a form of depression and since Anisman et al. teach depression, it would be obvious that Anisman et al. teach major depression.

Anisman et al. do not teach citalopram and ibuprofen for the treatment of major depression.

Van West et al. teach a method of treating major depression using antidepressants, specifically a selective serotonin reuptake inhibitor or SSRI (abstract and page 15). Van West et

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al. further teach that the anti-depressant, SSRI, has anti-inflammatory effects when used to treat major depression (page 15).

Sanchez et al. is solely used to teach that citalopram is a well known antidepressant drug belonging to the class of selective serotonin reuptake inhibitors or SSRIs (page 1, paragraphs [0001]-[0002]).

Thus it would be obvious that the SSRI in Van West et al. may be citalopram.

Lanza et al. teach a method of treating depression comprising a composition comprising ibuprofen (column 9, line 60; and column 18, lines 37-44).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the compounds of Anisman et al. to treat depression because the compounds of Van West et al. are antidepressants, namely SSRIs, and according to Van West et al., antidepressants, namely SSRIs, can be used to treat major depression.

The motivation to combine the compounds of Anisman et al. to the compounds of Van West et al. is that the compounds of Van West et al. are antidepressants, namely SSRIs, and that such compositions can be used to treat major depression.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the compounds of Van West et al. to contain citalopram and ibuprofen because the compounds of Sanchez et al. teach citalopram and the compounds of Lanza et al. teach ibuprofen and according to Van West et al., antidepressants, which act as anti-inflammatory agents, can be used to treat major depression and

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according to Lanza et al., ibuprofen is present in a composition that is used to treat major depression.

The motivation to combine the compounds of Van West et al. to the compounds of Sanchez et al. and Lanza et al. is that compounds of Sanchez et al. are antidepressants and the compounds of Lanza et al. are anti-inflammatory agents and that such compositions can be used to treat major depression.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

### ***Conclusion***

6. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh

S. Wang  
SHENGJUN WANG  
PRIMARY EXAMINER